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PHILIP S. JOHNSON			KISH, JAMES M	
JOHNSON & JOHNSON				
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NEW BRUNSWICK, NJ 08933-7003			3737	
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			09/26/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,626	REVIE ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 1-39 is/are pending in the application.
 - 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) Claim(s) ____ is/are allowed.
- 7) Claim(s) 1-39 is/are rejected.
- 8) Claim(s) ____ is/are objected to.
- 9) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on 06 September 2006 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/6/06</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the limitation stating "a control system configured to integrate the functionalities of a plurality of the parts of the surgical system; " is indefinite. It is unclear what "a plurality of parts of the surgical system" is directed towards. The same applies to "the plurality of parts" in the last two lines of claim 1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22 and 27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The broadest reasonable interpretation of a claim drawn to a computer readable medium (also called machine readable medium and other such variations) typically covers forms of non-transitory tangible media and transitory propagating signals per se in view of the ordinary and customary meaning of computer readable media, particularly when the specification is

silent. See MPEP 2111.01. A claim drawn to such a computer readable medium that covers both transitory and non-transitory embodiments maybe amended to narrow the claim to cover only statutory embodiments to avoid a rejection under 35 U.S.C. 101 by adding the limitation “non-transitory” (e.g. a non-transitory computer readable medium) to the claim.

Claim Rejections - 35 USC § 102

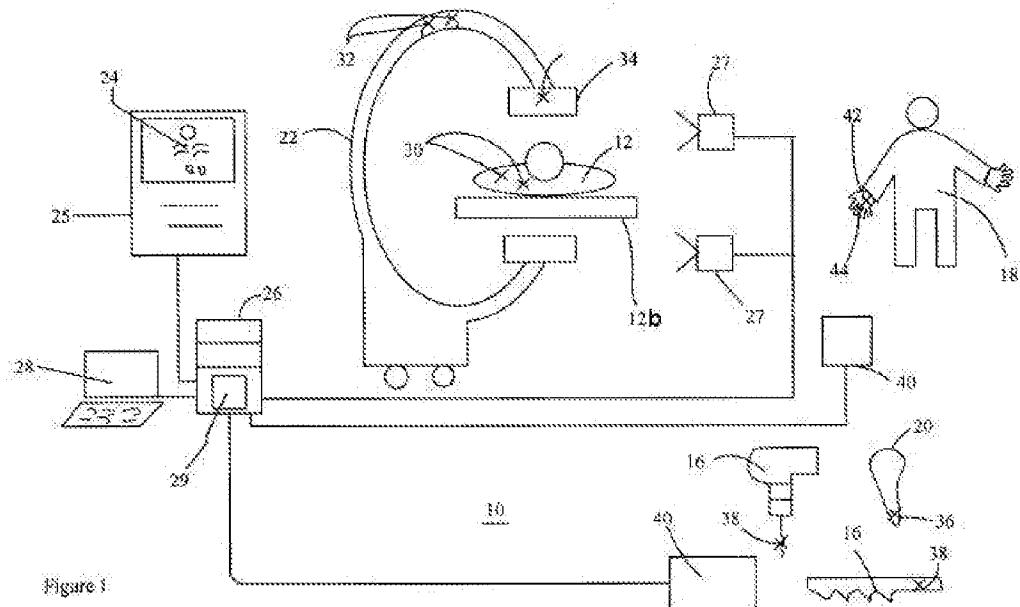
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 14-19, 22, 27-29, 31-33 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Sati et al. (WO 2004/001569) – herein referred to as Sati.

Sati discloses a computer assisted system for minimal invasive hip and knee surgery. Figure 1 of Sati is reproduced below and, unless stated otherwise, any references numerals refer to this reproduced Figure.



The system comprises a patient support **12b**; a wireless tracking system **27** and the tracking system can be magnetic (paragraph 39) with trackers **30** being attached to the patient and detected by the tracking system within a working volume of the tracking system; a registration system registers an anatomical image in the 3D framework established by the cameras (which refers to the tracking system) so that the relative movement between the instruments and patient can be displayed (see paragraphs 27 and 48); a first display device (either **25** or **28**); the computing device **26** obtains both images and tracking coordinates and/or other information and coordinates the many aspects of the system; Sati also comprises user interfaces **28** and numerals **40**.

Regarding claim 4, Sati describes in paragraph 41 that sensors are used to track the user's position and orientation and that a hand input device is used to report the

flexion and abduction of each of the fingers, along with wrist motion and utilized gesturally-based hand gestures to indicate the desired operation.

Regarding claim 5, paragraph 79 states that a heads-up display may be used while burring. In paragraph 78 a color map is described and this color map would therefore be displayed in the heads-up display.

Regarding claim 14, numeral **29** of Figure 1 illustrates a storage device in which images from the C-arm **22** are stored.

Regarding claim 15, 3D femoral stem and acetabular cup models are discussed in paragraph 36 and are projected onto x-ray images.

Regarding claims 16 and 17, 3D models of implants and instruments are discussed in paragraph 10.

Regarding claim 18, Sati utilizes an X-ray C-arm as illustrated in the Figures.

Regarding claims 19 and 22, the C-arm features movement about or along three axes, so that the patient can be easily approached from any direction. The pre-operative images may be a 3D dataset (see paragraph 81).

Regarding claims 27-29, Sati discusses workflow engine **38** in paragraph 40.

Regarding claim 36, Sati discusses a prosthesis that comprises two components in paragraph 54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sati in view of Hansen (US Patent No. 5,831,260). Sati describes the claimed invention except for explicitly stating that a second tracking system is used.

Hansen teaches a hybrid motion tracker in which both magnetic and infrared optical tracking systems are utilized simultaneously (see Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize both a magnetic and an infrared tracking system as taught by Hansen with the system of Sati because "the optical system which is more precise than the magnetic field system compensates for the magnetic field system and thereby achieves higher accuracy (see Abstract)... " and "By combining the two different technologies into one system, all of the advantages of the two systems by themselves are employed and none

of their disadvantages become detrimental, in particular, accuracy and dynamic performance are enhanced over results obtained through sole use of a magnetically based system (see Abstract).

Claims 3, 6-13 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati in view of Quaid, III (US Patent Pub. No. 2004/0024311) herein referred to as Quaid. Sati describes the claimed invention except for explicitly stating that the input device is a touch sensitive device.

Quaid teaches a system and method for haptic sculpting of physical objects. In paragraph 33, Quaid describes the system and states that many display devices and input devices may be used. "If desired, display device **30** may be a touch screen and be used as an input device." It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize Quaid's teaching of a touch screen device as the display and input system with the system of Sati as a mere matter of design choice ("if desired"), there being no unexpected results with such a choice.

Regarding claims 6 and 7, Figure 2 illustrates the display device as having at least four image regions. Furthermore, the image illustrated with Figure 2 is a captured image of the body part.

Regarding claim 8, Figure 1 of Quaid illustrates a display device and a support (see numerals **12**, **30**, **34**, and **36** and the unit they create). It would be obvious to one of ordinary skill in the art to utilize such a movable support in order to allow for flexibility of the operating area.

Regarding claim 9, Quaid teaches that the display device is in connection with the haptic device (see Figure 2). As stated in paragraph 27, the haptic device may be equipped with a component of interest including a camera.

Regarding claims 10 and 12, paragraph 37 of Quaid states that a real display of the surgical tool can be utilized by a remote surgeon. Therefore, it would be obvious that the camera component on the haptic device would provide a real-time display of the tool.

Regarding claim 11, Figure 2 of Quaid illustrates the display device as having at least four image regions. Furthermore, the image illustrated with Figure 2 is a captured image of the body part.

Regarding claim 13, Quaid states that a component of interest may be coupled to the haptic device and this may consist of a surgical light, a camera, an endoscope, etc. (see paragraph 27). These components are movable in the same manner as the haptic device. It would have been obvious to incorporate both a light and camera/endoscope (image capturing device) in order to allow a surgeon to operate remotely, as suggested by Quaid.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati as applied to claim 19 above, and further in view of Siczek et al (US Patent No. 5,515,416) – herein referred to as Siczek. Sati describes the claimed invention except for explicitly stating there is a first and a second source.

Siczek teaches a bi-place imaging device in which there are a first and second source and a first and second detector (*see the Figures*). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dual x-ray system taught by Siczek with the system of Sati because Sati teaches 3D imaging and Siczek's system allows for simultaneous viewing of a targeted object in two planes for three dimensional orientation (*see Abstract*) without the need for moving a single source and detector pair.

Regarding claim 21, Siczek teaches that the radiation axes are individually or simultaneously rotatable for placing them at the most advantageous imaging locations (*see Abstract*). Therefore, Siczek is capable of placing the two imaging pairs where ever necessary, including at locations above and below the patient and patient support.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati as applied to claim 1 above, and further in view of Mate et al. (US Patent Pub. No. 2002/0193685) – herein referred to as Mate. Sati discloses the claimed invention except for explicitly stating that the patient support is movable.

Mate teaches a guided radiation therapy system in which a magnetic tracking system determines the location of an implanted marker. “The support assembly includes a base, a support structure movably attached to the base, and a movement control device connected to the support structure in order to selectively move the support structure relative to the base (*see paragraph 12*).” It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a

movable support as taught by Mate with the system of Sati in order to allow repositioning of the patient for optimal placement for the surgical procedure.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sati in view of Siczek as applied to claim 21 above, and further in view of Betz et al. (US Patent No. 6,435,715) – herein referred to as Betz. Sati in combination with Siczek teaches the claimed subject matter except for the first and second e-ray sources provided in a floor.

Betz teaches a radiography device having an x-ray source and detector. In column 4, lines 35-36 Betz states that the robots that the source and detector are mounted to may be lowered into the floor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to lower the sources and detectors of Siczek into the floor, as taught by Betz, in order to conserve space in the operating room.

Claims 30, 34-35 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati as applied to claims 27 and 36 above, and further in view of Carson (US Patent Pub. No. 2002/0133175). Sati discloses the claimed subject matter except for identifying and differentiating objects attached to the fiducial markers.

Carson teaches a surgical navigation system for unicompartmental knee arthroplasty. Carson teaches a registration step in which the computer knows which body part, item or construct corresponds to which fiducial or fiducials and how the

position and orientation of the body part, item or construct is related to the position and orientation of its corresponding fiducial(s) (see paragraph 85). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate such an identifying component to the system of Sati in order to properly designate and illustrate on a monitoring display the patient and differentiate the patient from the surgical instruments in order to properly navigate and perform the surgery.

Regarding claims 34-35, see paragraph 71 of Carson as teaching that Fiducials may take the form of a screw driven into a bone or any other three dimensional item attached to another item, position and orientation of such three dimensional item able to be tracked in order to track position and orientation of body parts and surgically related items.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sati as applied to claim 1 above, and further in view of Carson and Mate. Sati discloses the claimed invention except for the means by which the fiducials are powered.

Carson teaches a surgical navigation system for unicompartmental knee arthroplasty. Carson states in paragraph 71 that inductive components may be utilized in fiducials (see the last sentence).

Mate teaches a guided radiation therapy system in which a magnetic tracking system determines the location of a wireless implanted marker. Mate teaches in paragraph 45 that the markers can be self-contained, powered markers that include a power source, such as a battery.

Therefore, it would be obvious to one of ordinary skill in the art to power the fiducial markers in the system of Sati via battery power (as taught by Mate) or by inductive power (as taught by Carson) as a matter of design choice, there being no unexpected results by either choice. Regarding the location within the surgical field that each type of fiducial is located, this is an intended use limitation that does not alter the system. Section 2113 of the MPEP states, "A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987.)"

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James Kish/
Primary Examiner, Art Unit 3737